RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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PHONE NUMBER:

TO EXAMINER:

ART UNIT:

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 305-3704

PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY FOR RESPONSES TO RESTRICTIONS.

COMMENTS: _____

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/776,190	01/24/97	JOSEL H	P564-7002

HM12/0427
NIKAIDO MARMELSTEIN MURRAY & ORAM
METROPOLITAN SQUARE
SUITE 330 G STREET LOBBY
655 FIFTEENTH STREET NW
WASHINGTON DC 20005-5701

EXAMINER	
RICIGLIANO,J	
ART UNIT	**PAPER NUMBER**
1627	21

DATE MAILED: 04/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/776,190	Applicant(s) Josel et al.
	Examiner Joseph W. Ricigliano Ph. D.	Group Art Unit 1627

☒ Responsive to communication(s) filed on *Jan 28, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *72-99* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *72-99* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions

Election/Restriction

1. This application contains claims directed to patentably distinct species of the claimed invention.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 72-89, drawn to a product conjugate, classified in at least class 530, subclasses 300+ and class 536 subclass 22.1+

II. Claims 95-99, drawn to a biospecific binding and immunoassay methods, classified in at least class 435, subclass 4+ (especially subclass 6) and class 436, subclass 501+, 506+ 518+, 536+ and 543+.

III. Claims 90-94, drawn to a processes of preparing a conjugate, classified in at least class 530, subclass 333+ and class 536 subclass 25.3+

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the product can be used to raise antibodies by injection into a subject animal.

4. Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product can be made by different processes such as by linking to the previously prepared peptided to hetero-bifunctional crosslinking agents with one reactive moiety, and subsequently attaching haptens etc. to the unmodified group of the linker.

5. Inventions II and III are related as distinct processes. The processes are distinct as the processes have different steps, (e.g., attachment of haptens to the carrier in group II as opposed to the binding assay steps wherein the immunoassay is correlated with the amount of binding partner) Moreover, the processes used different reagents (synthetic reagents as opposed to binding assay reagents) and produce different outcomes, a product carrier as opposed to an immunoassay result indicating the presence of an analyte.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search required each Group is not coextensive, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

7. If applicant elects the invention of group I applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently group I contains claims directed to the following patentably distinct species of the claimed invention comprised of the following subspecies:

A: Subspecies of synthetically made polymeric carrier/ monomeric units selected from nucleotides, nucleotide analogues and amino acids.

B: Subspecies of hapten molecules selected from the group consisting of at least: hormones, vitamins and neurotransmitters, peptides, nucleic acids etc.

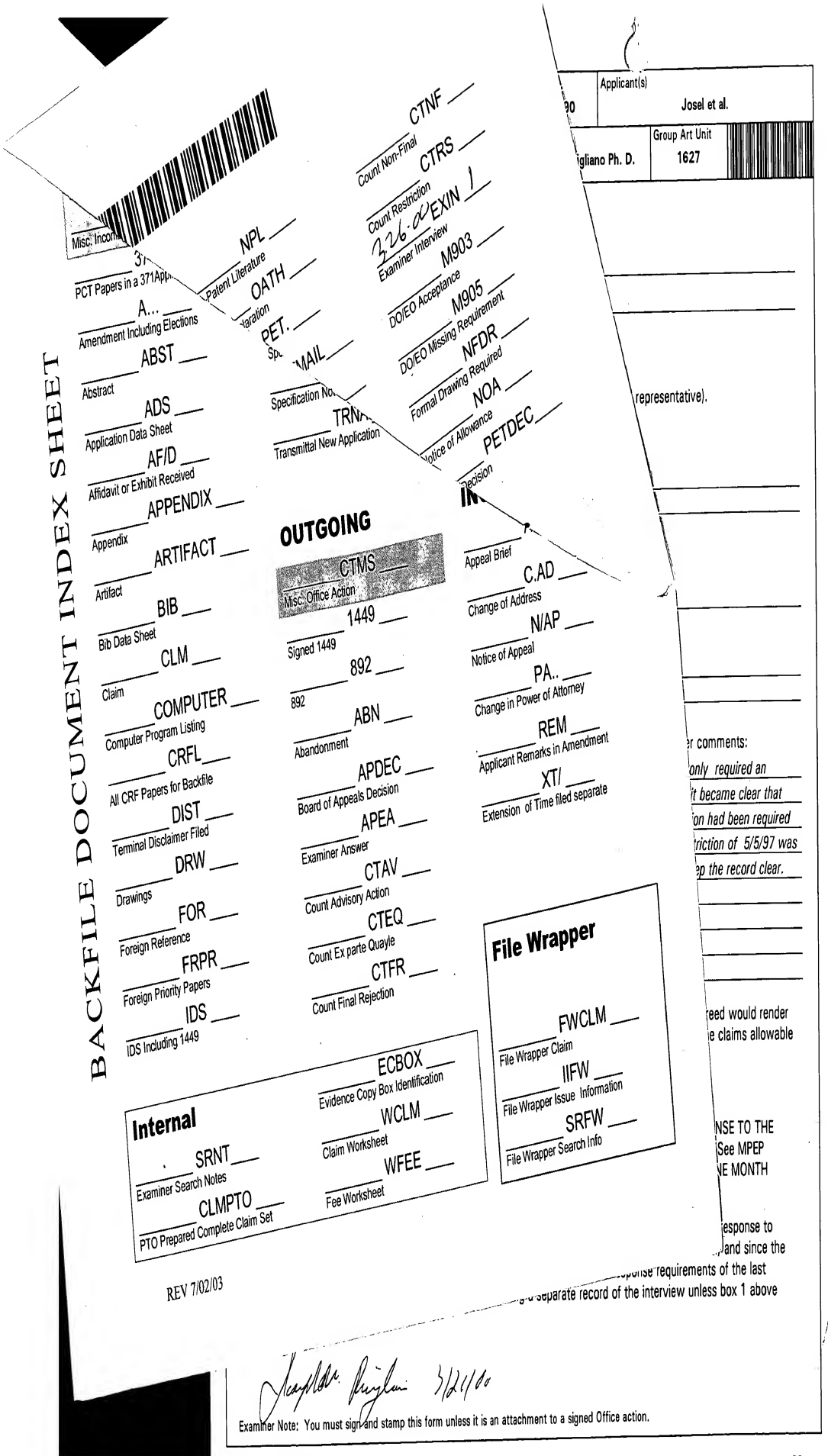
C: Subspecies of marker or solid phase binding groups selected from those disclosed including at least luminescent metal chelates and fluorescent groups etc.

A proper election of species requires a selection from subspecies A-C.

The species differ with respect to their chemical composition and the structure of the conjugates. Therefore, the groups have different issues regarding patentability and represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 72 is generic to group I.

8. If applicant elects the invention of group II applicant is required under 35 U.S.C. 121 to elect a single species of synthetically made polymeric carrier/ monomeric units (conjugate) selected from nucleotides, nucleotide analogues and amino acids.



BACKFILE DOCUMENT INDEX SHEET

Misc. Incom...
PCT Papers in a 371 App...
A... Amendment Including Elections
ABST Abstract
ADS Application Data Sheet
AF/D Affidavit or Exhibit Received
APPENDIX Appendix
ARTIFACT Artifact
BIB Bib Data Sheet
CLM Claim
COMPUTER Computer Program Listing
CRFL All CRF Papers for Backfile
DIST Terminal Disclaimer Filed
DRW Drawings
FOR Foreign Reference
FRPR Foreign Priority Papers
IDS IDS Including 1449
NPL Patent Literature
OATH ...laration
PET. Sp...
MAIL
Specification No...
TRN... Transmittal New Application

CTNF Count Non-Final
CTRS Count Restriction
EXIN Examiner Interview
M903 DO/EO Acceptance
M905 DO/EO Missing Requirement
NFDR Formal Drawing Required
NOA Notice of Allowance
PETDEC Decision
IN...

OUTGOING

CTMS Misc. Office Action
1449 Signed 1449
892 892
ABN Abandonment
APDEC Board of Appeals Decision
APEA Examiner Answer
CTAV Count Advisory Action
CTEQ Count Ex parte Quayle
CTFR Count Final Rejection

Appeal Brief
C.AD Change of Address
N/AP Notice of Appeal
PA.. Change in Power of Attorney
REM Applicant Remarks in Amendment
XT/ Extension of Time filed separate

File Wrapper

FWCLM File Wrapper Claim
IIFW File Wrapper Issue Information
SRFW File Wrapper Search Info

Internal

SRNT Examiner Search Notes
CLMPTO PTO Prepared Complete Claim Set
ECBOX Evidence Copy Box Identification
WCLM Claim Worksheet
WFEE Fee Worksheet

REV 7/02/03

Applicant(s)
Josel et al.
Group Art Unit
1627
...igliano Ph. D.

...representative).

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3/24/00

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.

U S Patent and Trademark Office
PTO-413 (Rev. 10-95)

Interview Summary

Paper No. 20

...eir chemical composition and the structure of
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...21 to elect a single disclosed species for
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...r clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph W. Ricigliano Ph. D. whose telephone number is (703) 308-9346. The examiner can be reached on Monday through Thursday from 7:00 A.M. to 5:30 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703) 308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith MacMillan, can be reached at (703) 308-0570.

Joseph W. Ricigliano Ph.D. 4/24/00

Examiner Joseph W. Ricigliano Ph. D.

Art unit 1627

April 26, 2000